REMARKS/ARGUMENTS

The present amendment is submitted in accordance with the Revised Amendment Format as set forth in the Notice provided on the USPTO web site for the Office of Patent Legal Administration; Pre-OG Notices; signed 1/21/03.

With entry of this amendment, claims 1-3, 9-13, and 15-20 are pending in the above-identified application. Claims 18-20 have been withdrawn from consideration. Claims 4 and 5 are canceled in order to expedite prosecution of the instant application and without acquiescence to the Examiner's rejections or reasons for rejection. Further, as described in detail below, claims 1-3, 9, 12, and 15-17 have been amended. Support for these amendments is identified in the following remarks. The specification has also been amended to correct certain typographical and clerical errors as well as to delete any browser-executable code. Applicants expressly reserve the right to prosecute the subject matter of claims 4 and 5, or of any other subject matter believed to be canceled by the amendments set forth herein, in a related, co-pending application. No new matter is believed to be added by these amendments.

In addition, further to the Examiner's remarks in the previous Office Action regarding the Information Disclosure Statement, Applicants will submit a copy of form 1449 previously filed by Applicants on Feb. 8, 2002, along with copies of publications numbered D8-D40, shortly.

Claims 1-3, 9, 12, and 15-17 have been amended to expedite prosecution and to set forth the invention with greater particularity. Claim 1 has been amended to recite with greater particularity an embodiment of the present invention wherein the polypeptide fragment encoded by the claimed nucleic acid "catalyzes the formation of trans-cinnamic acid by deamination of L-phenylalanine." Claim 1 has also been amended to recite that the nucleotide sequence encodes a "polypeptide" having the recited amino acid sequence or a fragment of the polypeptide. Support for these amendments can be found in the specification at, for example, page 3, lines 19-21; page 5, lines 6-10 and 16-19; page 6, lines 30-34; and page 7, lines 1-3.

Dependent claim 2 has also been amended by deleting the nucleotide sequence limitation reciting "of at least 18 base pairs up to the full length of the open reading frame encoding said amino acid sequence."

Dependent claim 3 has been amended to recite a particular portion of SEQ ID NO:3 which is the open reading frame for the encoded phenylalanine ammonia-lyase protein. Support for this amendment is found in the specification at, for example, page 6, lines 23 and 24.

Claim 10 has been amended to correct a minor typographical error by inserting a comma after "Claim 10" and deleting the comma after "wherein."

Claim 12 has been amended to clarify the subject matter as an "isolated nucleic acid construct." Support for this amendment can be found, for example, in original claim 9 from which claim 12 depends.

Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 1-5, 9-13 and 15-17 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejections of claims 4 and 5 are obviated by the cancellation of these claims as set forth above in the General Remarks. With respect to each of the pending claims standing rejected as allegedly indefinite, Applicants address the Examiner's remarks below.

Claim 1

The Examiner believes it is unclear whether the claimed fragments must also encode SEQ ID NO:1. To expedite prosecution, claim 1 has been amended to recite that the nucleic acid encodes a polypeptide having SEQ ID NO:1 or fragment of the polypeptide having a specified enzymatic activity. In light of these amendments, the rejection of claim 1 under 35 U.S.C. § 112, second paragraph, is obviated.

Claims 2 and 3

With respect to claims 2 and 3, the Examiner first believes that claim 2 does not further limit claim 1 because "claim 2 only requires 18 base pairs of the nucleotide sequence encoding SEQ ID NO:1." Also, the Examiner believes claims 2 and 3 to be indefinite because "it is not clear how a fragment consisting of 18-500 nucleotides can encode ... 711 amino acids," and because it is allegedly unclear whether the 18 base pairs (or 18-500 base pairs in the case of claim 3) is from SEQ ID NO:3 or from the nucleotide sequence encoding SEQ ID NO:1. The Examiner further contends that claim 3 is indefinite because claim 3 allegedly does not further limit claim 2.

In view of the amendment to claim 1 as described above, claim 2 cannot be reasonably interpreted as requiring that the claimed nucleic acids encode the full-length polypeptide of SEQ ID NO:1. Therefore, the isolated nucleic acid can comprise an active fragment of the nucleotide sequence of SEQ ID NO:3. Further, claim 2 has been amended as described above in the General Remarks to delete the term "at least 18 base pairs" and to require that the encoded fragments be enzymatically active. In light of these amendment, the instant rejections of claims 2 and 3 under 35 U.S.C. § 112, second paragraph, are obviated.

Claim 9

The Examiner asserts that the term "transcriptional initiation sequence" in claim 9 is indefinite. It is well-established that the determination of whether a claim is definite depends on whether those skilled in the art would understand the scope of the claim when the claim is read in light of the specification. *See North Am. Vaccine, Inc. v. American Cyanamid Co.*, 28 USPQ2d 1333, 1339 (Fed. Cir. 1993). The skilled artisan would understand the term "transcription initiation region," as used in the specification, to mean a promoter region, *i.e.*, a nucleotide sequence capable of initiating transcription of an operably-linked downstream sequence. (*See, e.g.*, page 17, lines 6 and 7 of the specification (where "transcription initiation control region" is referred to as "capable of promoting transcription"); and page 12, lines 5-7 (referring to promoter region of the LsPAL1 sequence as a transcription initiation region). Therefore, the phrase "transcription initiation region" as used in the specification is definite.

To expedite prosecution of the instant application, however, Applicants have amended claims 9, 11, and 12 to replace the term "transcription initiation region" with "promoter." Support for this amendment is found in the specification at, for example, page 17, lines 6 and 7; page 11, lines 13-15 and 21-34; page 12, lines 1-7; and page 15, line 11. Also, because this amendment is commensurate with the meaning of "transcription initiation region" as interpreted by the skilled artisan, this amendment does not change or limit the scope of claims 9, 11, or12.

Claim 10

The Examiner alleges that it is unclear how the terms "vector" and "construct" differ in claim 10. The term "vector" is typically used to refer to a nucleic acid molecule that self-replicates when transferred to a host cell and can be used as a vehicle for transferring a nucleic acid segment. A construct, on the other hand, generally refers to any nucleic acid that is formed from two or more different sources (*e.g.*, by cleaving with restriction enzymes and joining with a ligase). Further, the specification clearly refers to an expression construct of the present invention as comprising "a promoter functional in a host cell operably linked to a nucleic acid sequence encoding a phenylalanine ammonia-lyase." Thus, the artisan would understand that a "construct" can include, for example, an expression cassette (*e.g.*, a promoter region linked to a nucleic acid encoding a polypeptide, such as recited in claim 9), which can, for example, be inserted into a vector, such as recited in claim 10. Accordingly, claim 10 is definite.

To expedite prosecution of the instant application, however, Applicants have amended claims 9 and 10 to delete the term "nucleic acid construct" and insert the term "recombinant expression construct." Support for this amendment can be found in the specification at, for example, page 11, lines 10-14. Also, in view of the above remarks and because claim 9 as amended still recites a "promoter operably linked to a nucleic acid having the sequence set forth in SEQ ID NO:3," as recited in unamended claim 9, these amendments do not change or limit the scope of claims 9 and 10.

Claim 12

The Examiner states that claim 12 is an improper dependent claim because claim 11 is drawn to a transcription initiation sequence. Applicants respectfully note that claim 12 has been amended as described above in the General Remarks to clarify the subject matter as an "isolated nucleic acid construct." Therefore, the instant rejection is obviated.

The Examiner also asserts claim 12 to be indefinite because the phrase "wound induced expression" is allegedly unclear. The legal standard for definiteness under 35 U.S.C. § 112, second paragraph, requires that the Examiner analyze the claim in light of the specification as interpreted by one of ordinary skill in the art. *See, e.g., North Am. Vaccine*, 28 USPQ2d at 1339; MPEP § 2106 V(A)(2). In this case, the specification clearly conveys to the artisan the meaning of the phrase "wound induced expression" as expression of a nucleic acid that is induced in response to wounding. (*See, e.g.*, page 2, lines 10-12; page 3, lines 3-10 and 19-21; page 4, lines 4-15; page 5, lines 6-10 and 27-31; page 6, lines 4-10; and page 16, lines 15, 16, 18, and 19.) Therefore, the term "wound induced" in claim 12 is definite.

To expedite prosecution of the instant application, Applicants have amended claim 12 to recite that the "promoter induces expression of SEQ ID NO:3 in response to wounding." Support for this amendment is found in the specification at, for example, the pages and line numbers cited above. Also, because this amendment is commensurate with the meaning of the phrase "wound induced" as interpreted by the skilled artisan, this amendment does not change or limit the scope of claim 12.

Claim 15

With respect to claim 15, the Examiner alleges that the "metes and bounds of "enzymatically active fragment"' are not defined and also alleges that the term "altered" is unclear. Applicants respectfully traverse the instant rejection. The enzyme activity of phenylalanine ammonia-lyases is well known in the art and is disclosed in the specification. (*See, e.g.*, page 3, lines 19-21; page 5, lines 6-10 and 16-19; and Figures 1 and 11.) Accordingly, that the term "enzymatically active fragment" would be understood by the artisan reading the specification as a fragment capable of catalyzing the formation of trans-cinnamic acid by the

deamination of L-phenylalanine. Therefore, the term "enzymatically active fragment" in claim 15 is definite. Nonetheless, applicants have amended claim 15 to explicitly recite this activity. Since this term is commensurate with "enzymatically active", this amendment does not change or limit the scope of claim 15.

Further, because the term "altered" in claim 15 refers to "levels" of phenylalanine ammonia lyase in the cell, the skilled artisan reading the claim in light of the specification would understand the term "altered" to mean either an increase or decrease in phenylalanine ammonia-lyase expression. The specification describes both increase and decrease of endogenous expression using the nucleic acids of the present invention at, for example, page 14, lines 5-8; and page 16, lines 14-21. Thus, the term "altered" in claim 15 is definite.

To expedite prosecution, claim 15 has been amended to replace the term "altered" with the phrase "increase or decrease, " and to recite that the increase or decrease is "relative to the levels of phenylalanine ammonia-lyase endogenously expressed in said cell." Support for these amendments are found in the specification at, for example, page 3, lines 19-21; page 5, lines 16-19; page 14, lines 5-8; and page 16, lines 14-21. These amendments do not change or limit the scope of claim 15.

Claim 17

The Examiner asserts that the recitation "increase" in claim 17 lacks a comparative basis and that it is unclear where the "increase" takes place. Applicants respectfully traverse the instant rejection. It would be clear to the skilled artisan reading the claim in light of the specification that the "increase" in antifungal, antibacterial, or insecticidal activity is relative to such activity resulting from endogenous expression of phenylalanine ammonia-lyase in the cell. For example, on page 5, beginning at line 20, the specification discusses endogenous phenylalanine ammonia-lyase activity in plants and states, at lines 25-27 that "[p]ossession of the [phenylalanine ammonia-lyase gene allows manipulation by genetic engineering techniques to enhance or suppress its action[;]...[t]issue can now be produced with enhanced disease resistance ...." Further, because the specification states that "[i]ncreased activity of [the phenylpropanoid] pathway results in the synthesis and accumulation of phenolic compounds that contribute to ...

plant defense," the skilled artisan reading the specification would understand that the increased antifungal, antibacterial, or insecticidal activity would take place in tissues comprising the transgenic cells expressing the heterologous phenylalanine ammonia-lyase gene. Therefore, claim 17 is definite.

To expedite prosecution of the instant application, Applicants have amended claim 17 to recite that the increase in activity is "in the cell" and that "the increase is relative to the antifungal, antibacterial, or insecticidal activity resulting from the endogenous expression of phenylalanine ammonia lyase in said cell." Support for these amendments are found in the specification at, for example, page 5, lines 20-28; page 6, lines 1-3; and page 16, lines 14-21. Also, because this amendment is commensurate with the meaning of the terms "increase" as interpreted by the skilled artisan, this amendment does not change or limit the scope of claim 17.

The Examiner also states that "open reading frames" are not expressed and that the recitation of "open reading frame" in claims 15, 16, and 17 should be replaced with the term "nucleotide sequence." To expedite prosecution, claims 15, 16, and 17 have been amended as described above in the General Remarks to substitute the term "nucleotide sequence" for "open reading frame. Because these amendments are commensurate with the meaning of the term "open reading frame" as interpreted by the skilled artisan, these amendments do not change or limit the scope of claims 15, 16, or 17.

In view of the above remarks and amendments, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of claims 1-3, 9-13, and 15-17 under 35 U.S.C. § 112, second paragraph.

Written Description

Claims 4-5 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner notes that claims 4 and 5 are drawn to nucleic acid fragments that hybridize to SEQ ID NO:3 and encode enzymatically active fragments of SEQ ID NO:1. The instant rejection is obviated by the cancellation of claims 4 and 5 as set forth above in the

General Remarks. This rejection, remarks to the extent that the Examiner may believe that they apply to claims 1 or 15, as currently amended.

The Examiner asserts that Applicants have not presented a description of domains that are specific to SEQ ID NO:1 nor domains that are important for its function. Applicants respectfully disagree. It is well-established that written description is analyzed from the standpoint of the skilled artisan reading the specification. *See, e.g., Wang Labs v. Toshiba Corp.*, 26 USPQ2d 1767, 1774 (Fed. Cir. 1993). Thus, "an inventor is not required to describe every detail of his invention," and a disclosure "is sufficient to satisfy the requirement of section 112, first paragraph, when one skilled in the relevant art would understand what is intended and know how to carry it out." *See* MPEP § 2163 II(A)(3)(a)(i), *citing In re Hayes Microcomputer Products, Inc. Patent Litigation*, 25 USPQ2d 1241, 1246 (Fed. Cir. 1992).

As explained in the specification, at the time of the invention, phenylalanine ammonia-lyases were one of the best studied enzymes in plants. For example, the amino acid sequences were known for many phenylalanine ammonia-lyase isozymes. (*See, e.g.*, specification at, for example, page 4, lines 23-26, and Figure 2). It was further known that, at least among ten phenylalanine ammonia-lyases from diverse species, at least 125 amino acids are invariant; and further that 46 of these amino acids are also conserved with various species of histidase, an enzyme known to share a common mechanism of action with phenylalanine ammonia-lyase. (*See* Taylor and McInnes, *J. Biol. Chem.* 44:27473-27477, 1994, Figure 1 and page 27475, first paragraph, copy attached.) Amino acid sequence SEQ ID NO:1 of the present invention also shows significant structural homology with known phenylalanine ammonia-lyases, including the 46 invariant sites shown in Taylor and McInnes. For example, 45 of the 46 sites shown to be conserved between histidases and phenylalanine ammonia-lyases are also conserved in SEQ ID NO:1, with one site (319) showing a conservative change of leucine to isoleucine. The skilled artisan reading the specification would reasonably understand that the corresponding amino acids in SEQ ID NO:1 are sites important to enzyme function (*see, e.g.*, Taylor et al., *J. Biol. Chem.* 265:18192-18199, 1990 (stating that "[t]he degree of sequence similarity between the histidase and phenylalanine ammonia-lyase sequences is no doubt related to their functional similarities" (see page 18198, second full paragraph), and "the most conserved

regions are likely to be involved in catalysis or dehydroalanine formation" (Abstract))). In addition, other studies have also revealed certain residues in phenylalanine ammonia-lyases to be important. (*See, e.g.*, Langer *et al.*, *Biochemistry*, 36:10867-71, 1997 (demonstrating arginine 174 in parsley phenylalanine ammonia-lyase, a highly conserved residue, as important and close to the active site); Taylor and McInnes, *supra* (showing serine 254 in rat histidase, a residue invariantly conserved between histidases and phenylalanine ammonia lyases, to be essential for catalytic activity)).

Accordingly, because the disclosure of a polypeptide having SEQ ID NO:1 and its characterization as a phenylalanine ammonia-lyase in the specification reasonably conveys to the skilled artisan (1) structural information regarding conserved regions among isozymes as well as (2) structural information that correlates with functional attributes of phenylalanine ammonia-lyases, the artisan reading the specification would reasonably understand which residues and regions within a polypeptide having SEQ ID NO:1 are important.

In addition, as of the effective filing date, the skilled artisan would also understand that the tertiary structure of phenylalanine ammonia-lyases are highly conserved even after cleavage into fragments and that "large regions of the polypeptide backbone can be broken without loss of catalytic activity. (*See* Gilbert and Jack, *Biochem. J.* 199:715-23, 1981 (page 723, second and third full paragraphs).)

In addition to the structural information conveyed to the skilled artisan by disclosure of a phenylalanine ammonia-lyase having SEQ ID NO:1, routine assays for measuring activity of phenylalanine ammonia-lyases were also known as of the effective filing date. (*See, e.g.*, Rasmussen and Dixon, *supra* at page 1548 (citing Legrand *et al.*, *Phytochemistry* 15:1353-1359, 1976); Ke and Saltveit, *HortScience* 21:1169-1171, 1986 (cited in IDS)).

The method of making a claimed invention is also a factor in determining whether the artisan would reasonably believe that Applicants had "possession" of the claimed invention (MPEP § 2163 II(A)(3)(a)(i)). Moreover, a functional limitation that recites a specified activity for a claimed protein is appropriate where there is a known or disclosed assay for measuring the activity (*see, e.g.*, Synopsis of Application of Written Description Guidelines at Example 14). As set forth in the specification, fusion proteins comprising SEQ ID NO:1 were assayed using

the method described in Ke and Saltveit, *supra*, to confirm phenylalanine ammonia-lyase activity (*see, e.g.*, specification at page 21, lines 7-9), and the skilled artisan reading the specification would understand that such routine assays would also be used to confirm enzymatic activity of polypeptide fragments of the present invention. Further, applicants note that the tertiary structure of phenylalanine ammonia-lyase fragments

Therefore, in view of the knowledge in the art regarding phenylalanine ammonia-lyase, including knowledge regarding (1) important residues and regions within these enzymes as well as (2) routine assays for confirming the presence of catalytic activity, one of ordinary skill in the art reading the specification would readily accept that Applicants were in possession of enzymatically active fragments of the polypeptides of the present invention, including fragments corresponding to portions of SEQ ID NO:1.

Enablement

Claims 1-5, 9-13, and 15-17 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner alleges, *inter alia*, that Applicants have not reduced to practice their invention, that Applicants have not taught how one skilled in the art would use plants transformed with SEQ ID NO:3 nor how one skilled in the art would use SEQ ID NO:3 to generate a "specific agronomically important plant," and that Applicants have not specifically addressed how a cloned lettuce PAL "can be used in plant or any cell to achieve a specific phenotype or biological process." In addition, the Examiner believes that Applicants have not taught degenerate sequences encoding SEQ ID NO:1 and further believes that Applicants have not enabled a nucleotide sequence to be used as an antifungal, antibacterial, or insecticidal molecule. The Examiner also believes that hybridization reactions as well as transformation of plant cells with PAL cDNA cause unpredictable results.

With respect to claims 4 and 5, Applicants initially note that the instant rejection is obviated by the cancellation of claims 4 and 5 as set forth above in the General Remarks.

Applicants respectfully disagree with the Examiner's assertion regarding reduction to practice of the present invention. Applicants have isolated a nucleic acid encoding the amino acid sequence set forth in SEQ ID NO:1, and have therefore established an actual reduction to practice of at least this particular embodiment of the present invention. In addition, insofar as the Examiner has relied on an alleged absence of actual reduction to practice as a basis for rejecting the claims for lack of enablement, Applicants respectfully note that actual reduction to practice is not required for enabling support under 35 U.S.C. § 112, first paragraph. Reduction to practice can actual or constructive. *See, e.g., Hyatt v. Boone*, 47 USPQ2d 1128, 1130 (Fed. Cir. 1998); MPEP § 2138.05. The instant claims, including, *e.g.*, 1-5, 9-13, and 15-17, are actually or constructively reduced to practice and comply with the enablement requirement of 35 U.S.C. § 112, first paragraph, for reasons further set forth herein in response to the Examiner's remarks.

Further, the scope of enablement need "only bear a '*reasonable correlation*' to the scope of the claims." MPEP § 2164.08 at 2100-186 (emphasis added), *citing In re Fisher*, 166 USPQ 18, 24 (CCPA 1970). Accordingly, everything necessary to practice the invention need not be disclosed, MPEP § 2164.08 at 2100-186. Rather, "all that is necessary is that one skilled in the art be able to practice the invention, *given the level of knowledge and skill in the art*." *Id* (emphasis added).

In view of the above standards, Applicants have clearly taught how to use SEQ ID NO:3 to generate a "specific agronomically important plant." In the present case, the specification teaches, for example, the use of SEQ ID NO:3 and related sequences to produce recombinant expression constructs and vectors for expression of phenylalanine ammonia-lyase nucleotide sequences in plant cells; the specification also teaches that these nucleic acids can be used for production of transformed plants having a modified response to wounding, including, *e.g.*, reduced browning or increased plant defense mechanisms. (*See, e.g.*, page 5, lines 15-34; page 6, lines 1-10; and pages 11-19, in which the specification describes, for example, the use of nucleotide sequences of the present invention to produce transgenic plants having increased or decreased phenylalanine ammonia-lyase activity (*e.g.*, via expression of a heterologous sense or antisense PAL nucleic acid), as well as how phenylalanine ammonia-lyase activity correlates

with wound responses in plants such as tissue browning and plant defense.) Because recombinant DNA methods as well as methods of nucleic acid transfer and transgene expression were well-known as of the filing date, the skilled artisan reading the specification would have sufficient guidance for the production of transgenic plants having increased or decreased phenylalanine ammonia-lyase expression.

In this regard, Applicants respectfully disagree with the Examiner's reliance on Matsuda *et al.* (*Plant Cell Physiology* 37:215-222, 1996) as a basis for rejecting the instant claims. The Examiner states that Matsuda *et al.* teach that transforming tobacco with a potato PAL cDNA reduced fertility in some of the tobacco plants. As stated above, enablement only requires a *reasonable correlation* to the scope of the claims. *Fisher*, 166 USPQ at 24. Even assuming that an infertile plant can be considered evidence of non-enablement, Matsuda states that only ***some*** of the plants were infertile. It is well settled that the presence of some inoperative embodiments within the scope of a claim does not render a claim non-enabled where the skilled artisan "could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with the expenditure of no more effort than is normally required in the art." MPEP § 2164.08, *citing Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 224 USPQ 409, 414 (Fed. Cir. 1984).

In the present case, as the Examiner admits, Matsuda *et al.* teach that only some of the transformed tobacco plants had reduced fertility. Further, it was known that the reduced fertility was due to decreased PAL activity (*see* page 220, first column, 3rd full paragraph) and, therefore, was not due to ectopic PAL activity, as the Examiner contends. The reduced PAL activity was known, as of the effective filing date, to be due to sense suppression of the endogenous tobacco PAL genes that can be reversed in first generation (T_1) transformants to produce a transgenic plant that over expresses a heterologous phenylalanine-ammonia lyase. *See* Howles *et al.*, *Plant Physiol.* 112:1617-1624, 1996 (*passim*). Thus, the skilled artisan reading the specification would understand that sense suppression is a reversible phenomenon and that transgenic overexpression in a plant of phenylalanine ammonia-lyase can be achieved using the nucleotide sequences of the present invention.

With respect to claim 17, Applicants further disagree with the Examiner's assertion that "there is not a single molecule known that gives resistance to all fungi, or all bacteria or to all insects." The invention that one skilled in the art must be enabled to make under 35 U.S.C. § 112, first paragraph, is "that *defined by the claim(s)* of the particular application ...." MPEP § 2164 (emphasis added). In the instant case, claim 17 does not require the that the recited "antifungal, antibacterial, or insecticidal" activity "give resistance to *all* fungi, *all* bacteria, or *all* insects." In addition, during patent examination, the Examiner's interpretation of the claims must be reasonable and consistent with the interpretation that those skilled in the art would reach. *See In re Cortright*, 49 USPQ2d1464, 1468 (Fed. Cir. 1999); MPEP § 2111. the Examiner must explain why the skilled artisan reading the specification would interpret the phrase "antifungal, antibacterial, or insecticidal " to refer to a molecule having such activity against *all* bacteria, *all* fungi, or *all* insects. Such an interpretation is not reasonably consistent with the ordinary meaning of these terms.

Therefore, for the reasons set forth above, Applicants respectfully traverse the instant rejection of claims 1-3, 9-13, and 15-17 for allegedly lacking enabling support under 35 U.S.C. § 112, first paragraph. In view of the above remarks and amendments, Applicants respectfully request the Examiner to reconsider and withdraw the rejection.

Rejections under 35 U.S.C. §102

Claims 4 and 5 are rejected under 35 U.S.C. § 102(b) as being anticipated by Appert *et al.* (*Eur. J. Biochem.* 225:491-499 (1994)). The instant rejection is obviated by the cancellation of claims 4 and 5 as set forth above in the General Remarks.

Claim 12 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Okada *et al.* (September 1999, U.S. Patent No. 5,952,489). Because of the rejection of claim 12 as allegedly indefinite under 35 U.S.C. § 112, second paragraph, the Examiner has interpreted claim 12 to be directed to any promoter that induces expression of SEQ ID NO:3. In addition, the Examiner believes that Okada *et al.* anticipates claim 12 because the reference teaches "a promoter sequence that would also be considered a transcriptional initiation sequence and that could be used to induce expression of SEQ ID NO:3."

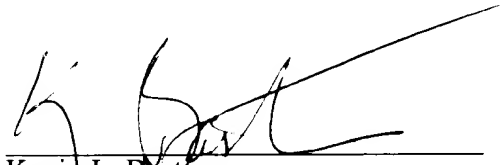
Applicants respectfully traverse the instant rejection. It is well-established that in order for a reference to anticipate a claim under 35 U.S.C. § 102(b), the reference must expressly or inherently disclose each and every limitation recited in the claim. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Therefore, the reference must disclose the "identical invention ... in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). In the present case, because claim 12 includes all of the limitations recited in claim 9, from which claim 12 depends, claim 12 requires that the promoter is "operably linked to a nucleic acid having the sequence set forth in SEQ ID NO:3." Therefore, Okada *et al.* does not anticipate claim 12 because the reference does not disclose a nucleic acid having SEQ ID NO:3.

In view of the above remarks and amendments, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of claim 12 under 35 U.S.C. § 102(b).

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at 415-576-0200.

Respectfully submitted,

By: 

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